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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-15-0052; NOP-15-12]

RIN 0581-AD39

National Organic Program (NOP);

Sunset 2016 Amendments to the National List

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following their April 2015 meeting. These recommendations pertain to the 2016 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the recommendations from the NOSB, this proposed rule would remove five non-organic nonagricultural substances from the National List for use in organic handling: egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-15-0052; NOP-15-12, and/or Regulatory Information Number (RIN) 0581-AD39 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry, impact information, etc.). Only relevant material supporting your position should be submitted. All comments received and any relevant background documents will be posted without change to <http://www.regulations.gov>.

Document: For access to the document and to read background documents or comments received, go to <http://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2642-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through

Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, email: bob.pooler@ams.usda.gov, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the USDA organic regulations, as indicated in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural substance

and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by the OFPA, recommendations to propose amendment of the National List are developed by the NOSB, operating in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to assist in the evaluation of substances to be used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. The OFPA also requires a sunset review of all substances included on the National List within five years of their addition to or renewal on the list. If a listed substance is not reviewed by the NOSB and renewed by the USDA within the five year period, its allowance or prohibition on the National List is no longer in effect. Under the authority of the OFPA, the Secretary can amend the National List through rulemaking based upon proposed amendments recommended by the NOSB.

The NOSB's recommendations to continue existing exemptions and prohibitions include consideration of public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s) as required by the OFPA. Recommendations to either continue or discontinue an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)) are determined by the NOSB's evaluation of technical information, public comments, and supporting evidence that demonstrate that the substance is: (a) harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; or (c) inconsistent with organic farming and handling practices.

In accordance with the sunset review process published in the Federal Register on

September 16, 2013 (78 FR 61154), this proposed rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB on April 30, 2015, to amend the National List to remove five substances allowed as ingredients in or on processed products labeled as “organic.” The exemptions of each substance appearing on the National List for use in organic production and handling are evaluated by the NOSB using the evaluation criteria specified on the OFPA (7 U.S.C. §§ 6517 – 6518).

II Overview of Proposed Amendments

Nonrenewals

After considering public comments and supporting documents, the NOSB determined that one substance exemption on § 205.605(a) and four substance exemptions on § 205.605(b) of the National List are no longer necessary for organic handling. AMS has reviewed and proposes to accept the five NOSB recommendations for removal. Based upon these NOSB recommendations, this action proposes to amend the National List to remove the exemptions for egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate.

Egg white lysozyme

The USDA organic regulations include an exemption on the National List for egg white lysozyme as an ingredient for use in organic processed products at § 205.605(a) as follows: egg white lysozyme (CAS # 9001-63-2). In 2004, egg white lysozyme was petitioned for addition to § 205.605 because it was considered to be an essential processing aid / preservative for controlling bacteria that survived the pasteurization process of milk that is used for cheese manufacture. As recommended by the NOSB, egg white lysozyme was added to the National List on September 12, 2006 (71 FR 53299).

As required by OFPA, the NOSB recommended the renewal of egg white lysozyme during their 2011 sunset review which was renewed by the Secretary on August 3, 2011 (76 FR 46595). The NOSB completed their most recent sunset review of the exemption of egg white lysozyme at their April 2015 meeting. Two notices of the public meetings on the 2016 sunset review with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). Their purpose was to notify the public that the egg white lysozyme exemption discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–14–0063 (October 2014 public meeting) and AMS – NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of egg white lysozyme the NOSB considered two technical reports on enzymes that were requested by and developed for the NOSB in 2011 and 2003, which are also available for review in the petitioned substance database on the NOP website.

The NOSB received no public comments supporting the continued need for the use of egg white lysozyme in organic processed products. Based upon the lack of public comments requesting the continued use of egg white lysozyme and supportive documents, the NOSB determined that the exemption for egg white lysozyme on the

National List in § 205.605(a) is no longer necessary or essential for organic processed products. Subsequently, the NOSB recommended removal of egg white lysozyme from the National List at their April 2015 public meeting.

AMS accepts the NOSB's recommendation on removing egg white lysozyme from the National List. This proposed rule would amend § 205.605(a) by removing the substance exemption for egg white lysozyme. This amendment is proposed to be effective on egg white lysozyme's current sunset date, September 12, 2016.

Cyclohexylamine

The USDA organic regulations include an exemption on the National List for cyclohexylamine as a processing aid for use in processed products at § 205.605(b) as follows: Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization. In December 2000, cyclohexylamine was petitioned for addition to § 205.605 for use as a boiler water additive in steam production for food processing facilities. As recommended by the NOSB, cyclohexylamine was added to the National List on September 12, 2006 (71 FR 53299). As required by OFPA, the NOSB recommended the renewal of cyclohexylamine during their 2011 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the cyclohexylamine exemption on the National List on August 3, 2011 (76 FR 46595). Subsequently, the exemption for cyclohexylamine as included on the National List was considered during the NOSB's 2016 sunset review. Two notices of the NOSB's public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). They notified the public that the cyclohexylamine exemption discussed in this proposed rule would expire on

September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–14–0063 (October 2014 public meeting) and AMS – NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. During their 2016 sunset review, the NOSB considered a technical report on cyclohexylamine that was requested by and developed for the NOSB in 2001, which is available for review in the petitioned substance database on the NOP website.

Within the September 2014 and April 2015 meeting notices, the NOSB requested information on the continued use of cyclohexylamine as a boiler water additive. Public comment in response to these requests provided the NOSB with limited information in support of the continued need for the use of cyclohexylamine as a boiler water additive in the production of organic processed products. As a result of the lack of support for the continued use of cyclohexylamine and the NOSB determination that the exemption for cyclohexylamine on § 205.605(b) is no longer necessary or essential for organic processed products, the NOSB recommended cyclohexylamine be removed from the National List at their April 2015 public meeting.

AMS accepts the NOSB's recommendation on removing cyclohexylamine from the National List. This proposed rule would amend § 205.605(b) by removing the

substance exemption for cyclohexylamine. This amendment is proposed to be effective on cyclohexylamine's current sunset date, September 12, 2016.

Diethylaminoethanol

The USDA organic regulations include an exemption on the National List for diethylaminoethanol as a processing aid for use in organic processed products at § 205.605(b) as follows: Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization. In December 2000, diethylaminoethanol was petitioned for addition onto § 205.605 for use as a boiler water additive in steam production for food processing facilities. As recommended by the NOSB, diethylaminoethanol was added to the National List on September 12, 2006 (71 FR 53299). As required by OFPA, the NOSB recommended the renewal of diethylaminoethanol during their 2011 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the diethylaminoethanol exemption on the National List on August 3, 2011 (76 FR 46595). Subsequently, the exemption for diethylaminoethanol was considered during the NOSB's 2016 sunset review. For the 2016 sunset review, two notices of the public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). Their purpose was to notify the public that the diethylaminoethanol exemption discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by

searching for the document ID numbers: AMS–NOP–14–0063 (October 2014 public meeting) and AMS – NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. In addition, during their 2016 sunset review, the NOSB considered a technical report on diethylaminoethanol that was requested by and developed for the NOSB in 2001, which is available for review in the petitioned substance database on the NOP website.

Within the September 2014 and April 2015 public meeting notices, the NOSB requested information on the continued use of diethylaminoethanol as a boiler water additive. Public comment in response to these requests provided the NOSB with limited information in support of the continued need for the use of diethylaminoethanol as a boiler water additive in the production of organic processed products. As a result of the lack of support for the continued use of diethylaminoethanol and the NOSB determination that the exemption for diethylaminoethanol on § 205.605(b) is no longer necessary or essential for organic processed products, the NOSB recommended diethylaminoethanol be removed from the National List at their April 2015 meeting.

AMS accepts the NOSB’s recommendation on removing diethylaminoethanol’s exemption from the National List. This proposed rule would amend § 205.605(b) by removing the substance exemption for diethylaminoethanol. This amendment is proposed to be effective on diethylaminoethanol’s current sunset date, September 12, 2016.

Octadecylamine

The USDA organic regulations include an exemption on the National List for

octadecylamine as a processing aid for use in organic processed products at § 205.605(b) as follows: Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization. In December 2000, octadecylamine was petitioned for addition onto § 205.605 for use as a boiler water additive in the steam production for food processing facilities. As recommended by the NOSB, octadecylamine was added to the National List on September 12, 2006 (71 FR 53299). As required by OFPA, the NOSB recommended the renewal of octadecylamine during their 2011 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the octadecylamine exemption on the National List on August 3, 2011 (76 FR 46595). Subsequently, the exemption for octadecylamine was considered during the NOSB's 2016 sunset review. For the 2016 sunset review, two notices of the public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). Their purpose was to notify the public that the octadecylamine exemption discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–14–0063 (October 2014 public meeting) and AMS – NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. In addition, during their 2016 sunset review, the NOSB considered a technical report on

octadecylamine that was requested by and developed for the NOSB in 2001, which is available for review in the petitioned substance database on the NOP website.

Within the September 2014 and April 2015 public meeting notices, the NOSB requested information on the continued use of octadecylamine as a boiler water additive. Public comment in response to these requests provided the NOSB with limited information in support of the continued need for the use of octadecylamine as a boiler water additive in the production of organic processed products. As a result of the lack of support for the continued use of octadecylamine and the NOSB determination that the exemption for octadecylamine on § 205.605(b) is no longer necessary or essential for organic processed products, the NOSB recommended octadecylamine be removed from the National List.

AMS accepts the NOSB's recommendation on removing octadecylamine from the National List. This proposed rule would amend § 205.605(b) by removing the substance exemption for octadecylamine. This amendment is proposed to be effective on egg white lysozyme's current sunset date, September 12, 2016.

Tetrasodium pyrophosphate

The USDA organic regulations include an exemption on the National List for tetrasodium pyrophosphate as an ingredient for use in organic processed products at § 205.605(b) as follows: Tetrasodium pyrophosphate (CAS # 7722-88-5)—for use only in meat analog products. In December 2001, tetrasodium pyrophosphate was petitioned for addition onto § 205.605 for use as an ingredient in organic food processing facilities. As recommended by the NOSB, tetrasodium pyrophosphate was added to the National List on September 12, 2006 (71 FR 53299). To implement OFPA requirements under the

sunset process, the NOSB recommended the renewal of tetrasodium pyrophosphate during their 2011 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the tetrasodium pyrophosphate exemption on the National List on August 3, 2011 (76 FR 46595). Subsequently, the exemption for tetrasodium pyrophosphate was considered during the NOSB's 2016 sunset review. For the 2016 sunset review, two notices of the public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). Their purpose was to notify the public that the tetrasodium pyrophosphate exemption discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–14–0063 (October 2014 public meeting) and AMS – NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. In addition, during their 2016 sunset review, the NOSB considered two technical reports on tetrasodium pyrophosphate that were requested by and developed for the NOSB in 2014 and 2002, which are available for review in the petitioned substance database on the NOP website.

Within the September 2014 and April 2015 meeting notices, the NOSB requested information on the continued use of tetrasodium pyrophosphate as an ingredient

necessary for use in organic food processing. The NOSB review of public comment in response to these requests indicated a lack of support for the continued need for tetrasodium pyrophosphate used as an ingredient in the production of organic processed products. In addition, based upon information from the 2014 technical report, the NOSB also determined there are several alternatives to tetrasodium pyrophosphate that maybe more compatible with organic production. Since the received comments indicated a lack of support for the continued use of tetrasodium pyrophosphate and the NOSB's determination of more suitable alternatives, the NOSB determined that the exemption for tetrasodium pyrophosphate on § 205.605(b) is no longer necessary or essential for organic processed products and recommended that tetrasodium pyrophosphate be removed from the National List.

AMS accepts the NOSB's recommendation on removing tetrasodium pyrophosphate from the National List. This proposed rule would amend § 205.605(b) by removing the substance exemption for tetrasodium pyrophosphate. This amendment is proposed to be effective on tetrasodium pyrophosphate's current sunset date, September 12, 2016.

III. Related Documents

Two notices of public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975) in order to notify the public that the 2016 sunset review listings discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary.

IV. Statutory and Regulatory Authority.

OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The current petition process was published on January 18, 2007 (72 FR 2167) and can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>. AMS published a revised sunset review process in the Federal Register on September 16, 2013 (78 FR 56811).

A. Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to

apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of OFPA (7 U.S.C. 6514(b)). States are also preempted under section 2104 through 2108 of OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 2108(b)(2) of OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 2121 of OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of

the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to prohibit the use of five non-organic non-agricultural substances that have limited public support and may no longer be used since non-organic non-agricultural alternatives to these substances may have been developed and implemented by food processors. AMS concludes that the economic impact of removing the nonorganic nonagricultural substance, egg white lysozyme, cyclohexylamine, diethylaminoethanol , octadecylamine, and tetrasodium

pyrophosphate would be minimal to small agricultural firms since alternative non-agricultural products may be commercially available. As such, these substances are proposed to be removed from the National List under this rule. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.¹ According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 19,470 in 2014. The list of certified operations is available on the NOP website at <http://apps.ams.usda.gov/nop/>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$39.1 billion in 2014, an 11.3 percent growth over 2013 sales.² In addition, the USDA has 80 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the

¹ U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey.

² Organic Trade Association. 2014. Organic Industry Survey. www.ota.com.

criteria established by the SBA. Certifying agents reported 27,810 certified operations worldwide in 2014.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35, or OMB's implementing regulations at 5 CFR part 1320.

E. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB for substances on the National List of Allowed and Prohibited Substances that, under the Sunset review provisions of OFPA, would otherwise expire on September 12, 2016. A 60-day period for interested persons to comment on this rule is provided. Sixty days is deemed appropriate because the review of these listings was widely publicized through two NOSB meeting notices; the use or prohibition of these substances, as applicable, are critical to organic production and handling; and this rulemaking must be completed before the sunset date of September 12, 2016.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and

records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is proposed to be amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. In § 205.605:

a. Paragraph (a) is amended by removing the following substance: Egg white lysozyme (CAS # 9001-63-2).

b. Paragraph (b) is amended by removing the following four substances:

Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization; Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization; Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization; and Tetrasodium pyrophosphate (CAS # 7722-88-5)—for use only in meat analog products.

Dated: December 8, 2015

Rex A. Barnes
Associate Administrator
Agricultural Marketing Service

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